

AMENDMENTS TO THE CLAIMS

1-25. (Previously canceled)

26. (Currently Amended) A sustained release formulation of an aqueous soluble biopolymer, wherein (i) the formulation is prepared by a process comprising exposure of the biopolymer in aqueous solution to an organic solvent under conditions resulting in a precipitate which releases the biopolymer in a sustained release fashion in aqueous solution, (ii) if the biopolymer is stabilized by a cation, the cation is a monovalent cation, and (iii) wherein the biopolymer's exposure to the organic solvent results in the formulation being one which provides a sustained release of the biopolymer.
27. (Previously Presented) The formulation of claim 26, wherein the biopolymer and a carrier protein in the aqueous solution are exposed to the organic solvent.
28. (Previously Presented) The formulation of claim 26 or 27, wherein the biopolymer is released from the formulation for a period of at least 24 hours.
29. (Canceled)
30. (Canceled)
31. (Previously Presented) The formulation of claim 28, wherein the period is at least 48 hours.
32. (Previously Presented) The formulation of claim 28, wherein the period is at least 7 days.
33. (Previously Presented) The formulation of claim 26 or 27, wherein the organic solvent is a polar protic organic solvent, and the formulation, when administered to a patient, releases said biopolymer at a rate which provides an average steady state concentration of at least the ED₅₀ for the biopolymer for a period of at least 2 days.
34. (Previously Added) The formulation of claim 33, wherein the period is at least 7 days.
35. (Previously Added) The formulation of claim 33, wherein the period is at least 14 days.

36. (Previously Added) The formulation of claim 33, wherein the period is at least 21 days.
37. (Previously Added) The formulation of claim 33, wherein the period is at least 50 days.
38. (Previously Added) The formulation of claim 33, wherein the period is at least 100 days.
39. (Previously Presented) The formulation of claim 26 or 27, wherein the organic solvent is an alcohol, an aldehyde, a ketone, a hydrocarbon, an aromatic hydrocarbon, or a mixture thereof.
40. (Previously Presented) The formulation of claim 26 or 27, wherein the organic solvent is an alcohol or mix of alcohols.
41. (Previously Presented) The formulation of claim 39, wherein the alcohol is a lower alcohol, or mixture thereof.
42. (Previously Presented) The formulation of claim 39, wherein the alcohol is selected from the group consisting of methanol, ethanol, isopropanol, n-propanol, n-butanol, isobutanol, and t-butanol, or a mixture thereof.
43. (Previously Presented) The formulation of claim 26 or 27, wherein the organic solvent is a polar protic solvent.
44. (Previously Presented) The formulation of claim 43, wherein the organic solvent is a water-miscible polar protic solvent.
45. (Previously Presented) The formulation of claim 33, wherein the organic polar protic solvent is water-miscible.
46. (Previously Presented) The formulation of claim 26 or 27, wherein the biopolymer is released from the formulation in vivo at a rate which provides an average steady state concentration of at least the ED₅₀ for the biologically active molecules or polypeptides for a period of at least 2 days.
47. (Previously Presented) The formulation of claim 46, wherein the period is at least 7 days.
48. (Previously Presented) The formulation of claim 46, wherein the period is at least 14 days.

49. (Previously Presented) The formulation of claim 46, wherein the period is at least 21 days.
50. (Previously Presented) The formulation of claim 46, wherein the period is at least 50 days.
51. (Previously Presented) The formulation of claim 46, wherein the period is at least 100 days.
52. (Previously Presented) The formulation of claim 26 or 27, wherein the organic solvent(s) are chosen such that, when administered to a patient, the solvent is released from the formulation at a rate which provides an average steady state concentration which remains at least one order of magnitude below the IC_{50} for deleterious side effects, if any, of the solvent.
53. (Previously Presented) The formulation of claim 26 or 27, wherein the biopolymer is selected from the group consisting of a peptide, a nucleic acid, an oligonucleotide, a carbohydrate, a ganglioside, or a glycan.
54. (Previously Presented) The formulation of claim 26 or 27, wherein the biopolymer is a polypeptide.
55. (Previously Presented) The formulation of claim 54, wherein the polypeptide is selected from the group consisting of cytokines, growth factors, somatotropin, growth hormones, colony stimulating factors, erythropoietin, plasminogen activators, enzymes, T-cell receptors, surface membrane proteins, lipoproteins, clotting factors, anticlotting factors, tumor necrosis factors, transport proteins, homing receptors, and addressins.
56. (Previously Presented) The formulation of claim 54, wherein the polypeptide is selected from the group consisting of rennin; human growth hormone; bovine growth hormone; growth hormone releasing factor; parathyroid hormone; thyroid stimulating hormone; lipoproteins; α -1-antitrypsin; insulin; proinsulin; follicle stimulating hormone; calcitonin; luteinizing hormone; glucagon; a clotting factor such as factor VIIIc, factor IX, tissue factor, and von Willebrand's factor; anti-clotting factors; atrial natriuretic factor; lung surfactant; a plasminogen activator; bombesin; thrombin; hemopoietic growth factor; tumor necrosis factor- α ; tumor necrosis factor- β ; enkephalinase; RANTES (regulated on

activation normally T-cell expressed and secreted); human macrophage inflammatory protein (MIP-1- α); a serum albumin; mullerian-inhibiting substance; relaxin A-chain; relaxin B-chain; prorelaxin; gonadotropin-associated peptide; a microbial protein; DNase; inhibin; activin; vascular endothelial growth factor (VEGF); receptors for hormones or growth factors; integrin; protein A; protein D; rheumatoid factors; a neurotrophic factor; platelet-derived growth factor (PDGF); a fibroblast growth factor; epidermal growth factor (EGF); transforming growth factors (TGF); insulin-like growth factor-I; insulin-like growth factor-II; des(1-3)-IGF-I (brain IGF-I); insulin-like growth factor binding proteins; CD proteins; erythropoietin; osteoinductive factors; immunotoxins; an interferon; colony stimulating factors (CSFs); interleukins (ILs); superoxide dismutase; T-cell receptors; surface membrane proteins; decay accelerating factor; antigens; transport proteins; homing receptors; addressins; regulatory proteins; immunoglobulin-like proteins; antibodies; and nucleases, or fragments thereof.

57. (Previously Presented) The formulation of claim 26 or 27, wherein biopolymer is selected from the group consisting of a lipid and a sterol.
58. (Previously Presented) The formulation of claim 26 or 27, wherein the biopolymer is an organic compound.
- 59-66. (Canceled)
67. (Previously Presented) A medicament for administration to an animal, comprising the formulation of claim 26 or 27.
68. (Previously Presented) The medicament of claim 67, for administration to a mammal.
69. (Previously Presented) The medicament of claim 67, for administration to a human.
70. (Previously Presented) A method for manufacturing a medicament comprising formulating the formulation of claim 26 or 27 with a pharmaceutically acceptable excipient.
- 71-72. (Canceled)
73. (Previously Presented) The formulation of claim 54, wherein the polypeptide is an interferon.

74. (Currently Amended) A sustained release formulation of an aqueous soluble biopolymer, wherein (i) if the biopolymer is stabilized by a cation, the cation is a monovalent cation, and (ii) the formulation is prepared by a process comprising exposure of the biopolymer in aqueous solution to an organic solvent under conditions resulting in a precipitate consisting essentially of the biopolymer, which precipitate releases the biopolymer in a sustained release fashion in aqueous solution.